

### **REMARKS**

Claims 1-55 are currently pending. Claims 1-18, 22-26, 30-51, 54 and 55 have been withdrawn from consideration. Claims 27, 29 and 53 have been cancelled herein. Therefore, claims 19-21, 28 and 52 are under consideration.

Applicants acknowledge Examiner's withdrawal of previously raised rejections based upon § 102(b), § 102(e) and § 103(a).

#### **Claim Amendments**

Claim 20 has been amended to remove the phrase "or a modification or derivative thereof." Claims 20, 21, 28 and 52 have been amended to recite "via the displacement of a leaving group." Support for this amendment can be found throughout the specification as-filed, for example, at page 4 lines 10-13, at page 6 lines 8-14, at page 38 lines 14-16 and Figure 1B. No new matter has been added by way of these amendments.

#### **Rejection of claims 20 and 21 under 35 U.S.C. § 112, second paragraph**

Claims 20 and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner is of the opinion that the phrase "a modification or derivative thereof" is unclear because the specification does not provide a standard for determining the scope of the genres of modifications or derivatives.

While not necessarily agreeing with the Examiner's reasoning, but rather in a good faith effort to expedite prosecution of the present application, Applicants have amended claim 20 to remove the phrase "or a modification or derivative thereof." Furthermore, Applicants point out that contrary to Examiner's assertion, previously presented claim 21 does not recite the phrase "or a modification or derivative thereof."

In light of the present amendment and argument, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 20 and 21 under 35 U.S.C. § 112.

Rejection of claims 27, 29 and 53 under 35 U.S.C. § 112, second paragraph

Claims 27, 29 and 53 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner is of the opinion that the phrase “the C-21 position of said drug” is without antecedent basis.

While not necessarily agreeing with the Examiner’s reasoning, but rather in a good faith effort to expedite prosecution of the present application, Applicants have cancelled claims 27, 29 and 53.

In light of the cancellation of claims 27, 29 and 53, the rejection of claims 27, 29 and 53 under 35 U.S.C. § 112 is rendered moot.

Rejection of claim 19 under 35 U.S.C. § 112, first paragraph

Claim 19 stands rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner is of the opinion that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. The Examiner asserts that claim 19 read broadly embraces a molecule with spermine attached directly to the C-21 of dexamethasone, but that the specification as filed discloses methods of conjugating spermine to dexamethasone through the use of conjugating reagents that leave a “bridge” between the C-21 of dexamethasone and spermine.

Applicants respectfully submit that the Examiner is improperly importing limitations from the specification into the claims. “Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.” *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004) (discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment); *E-Pass Techs., Inc.*

v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (“Interpretation of descriptive statements in a patent’s written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims ‘in view of the specification’ without unnecessarily importing limitations from the specification into the claims.”). See MPEP § 2111.01.

Here, the Examiner is improperly importing features of a specific example embodiment in the specification into claim 19. Previously presented claim 19 recites “a dexamethasone-spermine molecule and a lipid, wherein the spermine constituent of said dexamethasone-spermine molecule is attached through the C-21 position of the dexamethasone constituent of said dexamethasone-spermine molecule.” The as-filed specification describes an example dexamethasone-spermine molecule embodiment, wherein the conjugating reagent used to conjugate the dexamethasone constituent to the spermine constituent was Traut’s reagent, (see for example, Figure 1B and Example 1). Although for this example embodiment, the conjugating reagent leaves a “bridge” between the C-21 position of the dexamethasone constituent and the spermine constituent (see page 38 lines 20-26), one skilled in the art will know that other conjugating reagents could be employed to conjugate a spermine constituent through the C-21 position of a dexamethasone constituent, some of which other conjugating reagents not leaving a “bridge,” and some of which other conjugating reagents leaving a “bridge” that is different than the “bridge” left by Traut’s reagent in the example reaction.

In light of the above arguments, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 19 under 35 U.S.C. § 112.

Rejection of claims 20, 21, 28 and 52, under 35 U.S.C. § 112, first paragraph

Claims 20, 21, 28 and 52, stand rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner is of the opinion that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. The Examiner asserts that the claims are drawn to a genus of molecules with a steroid

conjugated to a polyamine via a conjugating agent that conjugates the polyamine through the C-21 of the steroid, but that the specification as filed was “generally directed to the modification of sterols comprising a C-21 hydroxyl group, or other C-21 reactive group,” but not to the C-21 of other steroids in which the C-21 group is a methyl group constituting a branch of C-20 where C-20 is also bonded to a linear chain of carbons comprising, for example, C-22 through C-26.

While not necessarily agreeing with the Examiner’s reasoning, but rather in a good faith effort to expedite prosecution of the present application, Applicants have amended claims 20, 21, 28 and 52, to recite “via the displacement of a leaving group.” Support for the displacement of various leaving groups at the C-21 position of a steroid can be found throughout the specification as-filed, for example, at page 4 lines 10-13 (where the leaving groups exemplified include hydroxyl, chlorine, mesylate, and tosylate), at page 6 lines 8-14 (where the leaving groups exemplified include hydroxyl), at page 38 lines 14-18 (where the leaving groups exemplified include hydroxyl and mesylate) and Figure 1B (where the leaving groups exemplified include hydroxyl). Although Applicants have not explicitly used the term “leaving group” in the specification, the term “leaving group” is well known among those of ordinary skill in the art. For example, in the textbook “Organic Chemistry” (Wade, L.G., Jr., 3d Ed., Prentice Hall, Upper Saddle River, New Jersey, 1987), “leaving group” is defined at page 291 as “the atom or group of atoms that departs during a substitution or elimination reaction. The leaving group can be charged or uncharged, but it departs with the pair of electrons that originally bonded the group to the remainder of the molecule.” One of ordinary skill in the art will also understand that although some leaving groups are less labile than others, that a less labile leaving group can readily be replaced with or converted to a more labile leaving group and that such a replacement or conversion is within the ordinary skill of the skilled artisan. Examples of “leaving groups” readily known to one having ordinary skill in the art include: hydroxy, methoxy, ethoxy, halogen (e.g., fluorine, chlorine, bromine and iodine), besylates, tosylate, mesylate, brosylates, nosylates, and triflates.

In light of the amendments and arguments, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 20, 21, 28 and 52 under 35 U.S.C. § 112.

Rejection of claims 27, 29 and 53, under 35 U.S.C. § 112, first paragraph

Claims 27, 29 and 53, stand rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner is of the opinion that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. The Examiner asserts that the claims are drawn to a genus of compounds with a polyamine conjugated to any drug through the C-21 position of a drug, but that the specification does not disclose conjugation to the C-21 position of any non-steroid drug.

While not necessarily agreeing with the Examiner's reasoning, but rather in a good faith effort to expedite prosecution of the present application, Applicants have cancelled claims 27, 29 and 53.

In light of the cancellation of claims 27, 29 and 53, the rejection of claims 27, 29 and 53 under 35 U.S.C. § 112 is rendered moot.

Summary

Applicants respectfully submit that the amendments made to the claims and the specification herein do not introduce new matter, and that the arguments set forth herein evidence that the pending claims are in full condition for allowance. Accordingly, favorable examination of the claims is respectfully requested at the earliest possible time.

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Respectfully submitted,  
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